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21  
22 UNITED STATES DISTRICT COURT  
23 SOUTHERN DISTRICT OF CALIFORNIA

24 CADENCE PHARMACEUTICALS,  
25 INC. and SCR PHARMATOP,

26 Plaintiffs,

27 v.

28 FRESENIUS KABI USA, LLC,

Defendant.

CASE NO. 13-CV-00139 DMS (MDD)

EXHIBIT 2 TO THE  
DECLARATION OF STEPHEN P.  
SWINTON IN SUPPORT OF  
PLAINTIFFS' RESPONSE TO  
FRESENIUS'S OBJECTION TO  
MAGISTRATE JUDGE DEMBIN'S  
ORDER STRIKING THE MARAIS  
REPORT

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30 AND RELATED COUNTERCLAIMS

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# **EXHIBIT 2**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

BEFORE HONORABLE DANA M. SABRAW, JUDGE PRESIDING

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CADENCE PHARMACEUTICALS, INC., ET AL., )  
VS. ) CASE NO. 13CV0139-DMS  
PLAINTIFF, )  
FRESENIUS KABI USA, LLC, ) SAN DIEGO, CALIFORNIA  
DEFENDANT. ) NOVEMBER 4, 2013  
   ) 9:00 A.M. CALENDAR

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REPORTER'S TRANSCRIPT OF PROCEEDINGS

CLAIM CONSTRUCTION HEARING

REPORTED BY:

LEE ANN PENCE, OFFICIAL COURT REPORTER  
UNITED STATES COURTHOUSE  
333 WEST BROADWAY ROOM 1393  
SAN DIEGO, CALIFORNIA 92101

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ALSO PRESENT:

HAZEL AKER, ESQ.

1 FOREST. I THINK, ALTHOUGH IN VERY SIMPLE NONCHEMICAL TERMS,  
2 IS REALLY THE SUBSTANCE OF WHAT THE DEFENDANTS ARE ARGUING.  
3 THEY ARE ARGUING TWO THINGS THAT WE THINK ARE WRONG IN THE  
4 INTRINSIC EVIDENCE, WRONG IN THE SCIENCE.

5 THEY ARGUE, FIRST, THAT A BUFFER CAN ONLY BE A  
6 BUFFER IF IT ACTUALLY ACTS ON AN EXOGENOUS ACID OR BASE,  
7 THEREFORE A BUFFER -- A BUFFERING AGENT THAT MIGHT BE A  
8 BUFFERING AGENT IN SOME OTHER SAMPLE OF THE SAME FORMULATION  
9 OR --

10 (ALARM TEST)

11 **THE COURT:** ALL RIGHT.

12 **MR. SWINTON:** OR THE OTHER ALTERNATIVE, EVEN IN A  
13 BUFFERING -- THE SAME AGENT IN ANOTHER FORMULATION WAS  
14 ADMITTEDLY A BUFFERING AGENT IF IT IS NOT ACTUALLY BEING --  
15 ACTING UPON SOME ACID OR BASE THAT MAKES ITS WAY INTO THE  
16 FORMULATION THEN IT IS NOT A BUFFER.

17 WE DON'T BELIEVE THAT IS SUPPORTED BY THE  
18 SPECIFICATION OR CHEMISTRY.

19 AND THEN SECONDLY THEY ARGUE THAT -- AND I WILL  
20 ADDRESS BOTH OF THESE. THEY ARGUE THAT IN ORDER TO BE A  
21 BUFFER A BUFFERING AGENT MUST HOLD A PRECISE PH, THAT IT MUST  
22 MAINTAIN A PRECISE PH. AND, AS I WILL SHOW, EVEN THE  
23 DICTIONARY DEFINITIONS UPON WHICH THEY RELY DISPUTE THAT  
24 CONCEPT.

25 SO AGAIN, THE CLAIM LANGUAGE THAT WE HAVE IN FRONT

1 OF US MERELY REFERS TO A BUFFERING AGENT. THE SPECIFICATION  
2 DOES NOT HAVE ANY LIMITING LANGUAGE THAT WOULD PROVIDE ANY  
3 BASIS FOR THE DEFENDANTS TO READ IN THE LIMITATIONS THAT THEY  
4 OFFER. PRETTY STRAIGHTFORWARD.

5 AND, INDEED, IN THE SPECIFICATION IS THE -- IS AT  
6 LEAST THE FIRST INDICATION, AS WE WILL SEE IN THE CLAIMS, THAT  
7 THE PATENTEE ANTICIPATED THAT THE BUFFERED RANGE FOR THE  
8 CLAIMED FORMULATIONS WOULD RUN ANYWHERE FROM 4 TO 8, NOT BEING  
9 HELD AT A SPECIFIC LEVEL AT ALL.

10 NOW, HERE IS THE DEFENDANTS' DICTIONARY DEFINITION  
11 THAT THEY PROFFERED FOR THIS -- FOR THE SUPPORT FOR THEIRS IS,  
12 I THINK, THE BEST EVIDENCE THAT THE IDEA THAT A BUFFERING  
13 AGENT HAS TO RESIST ALL CHANGE IN PH IS IMPOSSIBLE IN A  
14 CHEMICAL SENSE AND NOT REALISTIC FROM THE REAL WORLD SENSE.  
15 AND, IN FACT, THAT IS WHAT IS REFLECTED IN THEIR DEFINITION.

16 THEIR CITED DICTIONARY DEFINITION FROM STEDMAN'S  
17 MEDICAL DICTIONARY FOR BUFFER HAS THIS STATEMENT: A MIXTURE  
18 OF AN ACID AND ITS CONJUGATE BASE --

19 AND I WILL SKIP OVER THE CHEMISTRY.

20 -- THAT, WHEN PRESENT IN A SOLUTION, REDUCES ANY  
21 CHANGES IN PH THAT WOULD OTHERWISE OCCUR IN THE SOLUTION.

22 WE DIDN'T MAKE THAT UP. WE BELIEVE THAT IS  
23 ACCURATE. A BUFFERING AGENT WILL REDUCE CHANGES IN PH BUT IT  
24 DOES NOT GUARANTEE THAT THERE WON'T BE ANY CHANGES IN PH. AND  
25 YET THAT IS PRECISELY THE CRUX OF THE ARGUMENT THAT THEY MAKE,

1                   **MR. SWINTON:** AGAIN, OUR INTENT BY THE "CAN" TO BE  
2 ADDED TO JUDGE STARK'S DEFINITION WAS NOT INTENDED TO UPSET  
3 HIS DEFINITION OR TO EXPAND WHAT WE BELIEVE TO BE, AND JUDGE  
4 STARK RULED TO BE, THE ESSENCE OF A BUFFERING AGENT AS CLAIMED  
5 IN THESE PATENTS.

6                   AND AS A RESULT, AS I SAID, WE WOULDN'T WALK OUT OF  
7 THE COURTROOM THINKING JUSTICE HADN'T BEEN DONE IF WE KEPT  
8 THAT. WE JUST KNOW, FROM THE FIGHTS WE SAW IN DELAWARE, THAT  
9 THERE WERE -- THESE SAME ARGUMENTS WILL RECIRCULATE HERE  
10 UNLESS WE ADOPT THIS SLIGHT MODIFICATION THAT STILL FINDS  
11 FAVOR WITH JUDGE STARK'S RULING.

12                  **THE COURT:** THAT WOULD BROADEN THE CLAIM, WOULD IT  
13 NOT?

14                  **MR. SWINTON:** I DON'T THINK IT BROADENS THE CLAIM.  
15 IN FACT, MY FINAL SLIDE SHOWS WHY IT DOESN'T BROADEN THE  
16 CLAIM.

17                  THAT IS, AGAIN, IT IS NOT A QUESTION -- THIS IS AN  
18 EXAMPLE OF CLAIM 3 FROM THE PATENT IN WHICH THE PATENTEE MADE  
19 CLEAR THAT THE -- AT LEAST UNDER CLAIM 4 THE PH RANGE COULD  
20 RUN FROM 4 TO 8 ON THE PH SCALE FOR THE CLAIMED FORMULATION.  
21 AS A DEPENDENT CLAIM ON WHAT CLAIM 1 CLAIMED AS A BUFFERING  
22 AGENT IN THE FIRST PLACE, THERE IS NOTHING HERE THAT SAYS THE  
23 BUFFERING AGENT HAS TO HOLD THE PH AT A PARTICULAR POINT. IN  
24 FACT, THE ESSENCE OF THE RANGE THERE, WE THINK, ANTICIPATES  
25 THAT. SO THEREFORE IT DOESN'T BROADEN THE CLAIM TO MERELY

1 INDICATE THAT IT CAN HELP RESIST CHANGE AS OPPOSED TO HAVING  
2 TO ACTUALLY RESIST CHANGE IN THOSE CASES WHERE THERE MAY NOT  
3 BE AN ACID OR A BASE ADMITTED INTO THE FORMULATION AFTER IT IS  
4 MADE.

5 **THE COURT:** THANK YOU.

6 **MR. SWINTON:** THANK YOU.

7 **THE COURT:** ALL RIGHT.

8 MR. BENNETT.

9 **MR. BENNETT:** YOUR HONOR, I AM BRIEFLY GOING TO  
10 ADDRESS THIS ISSUE OF THE ADDITION OF "CAN" BECAUSE, AS THE  
11 FOCUS OF MR. SWINTON'S PRESENTATION, I DO THINK IT IS A  
12 PROBLEM. I DO THINK IT BROADENS THE CLAIM.

13 AS WE STATED IN OUR BRIEFING, YOU KNOW, ONE PROBLEM  
14 HERE IS THAT IT REALLY OPENS THE DOOR TO THE POSSIBILITY OF  
15 THEM ARGUING THAT EVEN A SUBSTANCE THAT HAS A THEORETICAL  
16 IMPACT IN RESISTING PH, EVEN IF THERE IS NO SCIENTIFIC PROOF  
17 THAT IT DOES, COULD INFRINGE THE CLAIM.

18 AND IT ALSO OPENS THE DOOR OF IT RESISTING, REALLY,  
19 IN FINDING INFRINGEMENT IF THERE IS ANY CHANGE -- ANY  
20 RESISTANCE TO CHANGE OF PH ANYWHERE ON THE PH SCALE WHICH, FOR  
21 REASONS THAT I WILL EXPLAIN IN A MINUTE, REALLY DON'T MAKE  
22 SENSE WHEN YOU READ THIS PATENT AS A WHOLE.

23 NOW, A BRIEF BIT OF CONTEXT.

24 AS YOU KNOW, YOUR HONOR, WE ARE CONTESTING IN THIS  
25 CASE THAT OUR PRODUCT DOES NOT CONTAIN A BUFFERING AGENT. AND